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ELF ATOCHEM NORTH AMERICA, INC.
900 First Avenue, P.O. Box 1536
King of Prussia, PA 19406-0018

Tel: 215-337-6500

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October 12, 1992

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CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed final report on a study to establish eye irritation potential in rabbits for trimethyl-2-carbamylethyltin to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study report is considered confidential business information of Atochem.

The enclosed study report provides information on the chemical trimethyl-2-carbamylethyltin. Its exact chemical name is 3-(trimethylstannyl)propamide and its CAS number is 60522-55-6.

The title of the enclosed study report is Acute Range-Finding Toxicity Studies With Trimethyl-2-Carbamylethyltin, Lot No. 3676-33-1. This report consists of several studies. The following is a summary of the adverse effects observed in the eye irritation study.

One-tenth (0.1) gram of trimethyl-2-carbamylethyltin was instilled into the right eye of each of three New Zealand albino rabbits. All test animals died within 3 hours after test material application.

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To our knowledge, Atochem has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

TR91-786

3

Industrial BIO-TEST Laboratories, Inc.
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

May 12, 1976

Mr. Arthur W. Sheldon
Director of Safety and Environmental Affairs
M & T Chemicals, Inc.
Subsidiary of American Can Company
Rahway, New Jersey 07065

T-628

Dear Mr. Sheldon:

Re: IBT No. 8530-08644 - Acute Range-Finding Toxicity Studies with Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1

We are submitting herewith our laboratory reports prepared in connection with the above studies.

Very truly yours,

J. C. Calandra

JCC:trm

J. C. Calandra
President

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REPORT TO

M & T CHEMICALS, INC.

Range-Finding Acute Oral Toxicity Study - Female Albino Rats

Results

IBT No.: 8530-08644
Test Material: Trimethyl-2-carbamylethyltin
Lot No. 3676-33-1
Physical Description: White powder
Form Administered: As propylene glycol solutions; 1.0 percent (w/v) at 10 through 100 mg/kg, 10.0 percent (w/v) at 300 mg/kg and 30.0 percent (w/v) at 1,000 and 3,000 mg/kg

Classification: Highly Toxic
Approximate Acute Oral Lethal Dose = >10 <30 mg/kg

I. Mortality and Body Weight Data

Dose Level (mg/kg)	Animal Number	Individual Body Weights (g) Test Day Number 0	14	Number Dead / Number Tested	Percent Dead
10	1	176	227	0/1	0
30	2	186	(10 Days)	1/1	100
100	3	188	(2 Days)	1/1	100
300	4	182	(1 Day)	1/1	100
1,000	5	188	(6-22 Hours)	1/1	100
3,000	6	174	(1-1/2 Hours)	1/1	100

Note: Figures in parentheses indicate time of death.

II. Reactions and Pathology

The pharmacotoxic symptoms exhibited by the rats post-oral administration of the test material are presented in the table on the following page:

Necropsy examination of the animals that died revealed red, discolored lungs. In addition, intestinal hemorrhages, enlarged kidneys and emaciation were revealed in animal No. 2 and intestinal hemorrhages were revealed in animal No. 6. Examination of the survivor did not reveal any gross pathologic alterations.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by: Wendy A. Harrison
Wendy A. Harrison, B.S.
Assistant Group Leader
Acute Oral and Parenteral Toxicity

Report approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

trm

5/12/76

TABLE

Range-Finding Acute Oral Toxicity Study - Female Albino Rats

Summary of Reactions

IBT No.: 8530-08644
Test Material: Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1
Form Administered: As propylene glycol solutions; 1.0 percent (w/v) at 10 through 100 mg/kg, 10.0 percent (w/v) at 300 mg/kg and 30.0 percent (w/v) at 1,000 and 3,000 mg/kg

	Dose Levels (mg/kg):											
	10		30		100		300		1,000		3,000	
Reactions	O	R	O	R	O	R	O	R	O	R	O	R
Hypoactivity	5 M	2 D	5 M	2 D	5 M	N	5 M	N	5 M	N	5 M	N
Labored breathing	-	-	-	-	15 M	N	15 M	N	15 M	N	5 M	N
Muscular weakness	-	-	-	-	15 M	N	15 M	N	15 M	N	5 M	N
Ataxia	-	-	-	-	-	-	-	-	-	-	10 M	N
Lacrimation	-	-	-	-	6-22 H	N	6-22 H	N	-	-	15 M	N
Prostration	-	-	-	-	-	-	-	-	-	-	15 M	N
Ptosis	-	-	-	-	6-22 H	N	6-22 H	N	-	-	20 M	N
Vasodilation	-	-	-	-	-	-	-	-	-	-	20 M	N
Salivation	-	-	-	-	-	-	20 M	2 H	20 M	2 H	-	-
Ruffed fur	-	-	-	-	6-22 H	N	6-22 H	N	-	-	-	-
Tremors	-	-	5 D	N	1 D	N	-	-	-	-	-	-
Hyperirritability	-	-	4 D	N	-	-	-	-	-	-	-	-
Convulsions	-	-	9 D	N	-	-	-	-	-	-	-	-

O = Onset
R = Recovery
- = No Reaction

D = Days
H = Hours

M = Minutes
N = No Recovery

RANGE-FINDING ACUTE ORAL TOXICITY STUDY - ALBINO RATS

Young albino rats derived from Sprague-Dawley stock were used as test animals. All animals were kept under observation for 5 days prior to experimental use, during which period they were checked for general health and suitability as test animals. The animals were housed in stock cages and were permitted a standard laboratory diet plus water ad libitum, except during the 16-hour period immediately prior to oral intubation when food was withheld.

A range of several dose levels was studied using 1 rat per level. All doses were administered directly into the stomach of the rats using a hypodermic syringe equipped with a ball-tipped intubating needle.

After oral administration of the test material, the rats were housed individually in suspended, wire-mesh cages and observed for the following 14 days. Initial and final body weights, mortalities and reactions were recorded. A necropsy examination was conducted on all animals.

At the end of the observation period, the approximate acute oral lethal dose of the test material was determined. The test material was then assigned a classification in accordance with Harold C. Hodge*. The classification system is presented below:

Approximate Acute Oral Lethal Dose (Range of Values)	Classification	Probable Lethal Dose for a 70 kg Man in Commonly Used Measures
Less than 5 mg/kg	Extremely toxic	a taste (less than 7 drops)
5 - 50 mg/kg	Highly toxic	between 7 drops and 1 teaspoonful
50 - 500 mg/kg	Moderately toxic	between 1 teaspoonful and 1 ounce
500 - 5,000 mg/kg	Slightly toxic	between 1 ounce and 1 pint or 1 pound
5,000 - 15,000 mg/kg	Practically nontoxic	between 1 pint and 1 quart
Greater than 15,000 mg/kg	Relatively harmless	more than 1 quart

* Hodge, Harold C., "The LD_{50} and Its Value," American Perfumer and

REPORT TO

M & T CHEMICALS, INC.

Range-Finding Acute Dermal Toxicity Study - Male Albino Rabbits

Results

IBT No.: 8530-08644
Test Material: Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1
Physical Description: White Crystals
Form Administered: Applied as a slurry in 3.0 percent (w/v) aqueous methylcellulose

Classification: Highly Toxic
Approximate Acute Dermal Lethal Dose < 200 mg/kg

I. Mortality and Body Weights

Dose Level (mg/kg)	Animal Number	Individual Body Weights (kg) Test Day Number: 0	7	14	Number Dead / Number Tested	Percent Dead
200	1*	2.92	(23 hours)	-	1/1	100
500	2*	2.86	(6-22 hours)	-	1/1	100
2,000	3*	2.58	(4 hours)	-	1/1	100

Note: Figures in parentheses indicate time of death.

* The skin at the site of application was abraded.

II. Reactions and Pathology

The pharmacotoxic symptoms exhibited by the rabbits following dermal exposure to Trimethyl-2-carbamylethyltin are presented in the table on the following page.

Necropsy examination of the animals that died revealed focal hemorrhages in the lungs and dilated capillaries on the surface of the kidneys in rabbit No. 3. Advanced postmortem autolysis was observed in rabbit Nos. 1 and 2.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Prepared by: Helfried Paa
Helfried Paa
Assistant Group Leader
Acute Toxicity

Approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

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5/12/76

TABLE

Range-Finding Acute Dermal Toxicity Study - Male Albino Rabbits

Summary of Reactions

IBT No.: 8530-08644
Test Material: Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1
Form Administered: Applied as a slurry in 3.0 percent (w/v) aqueous methylcellulose

	Dose Levels (mg/kg)					
	200		500		2,000	
Reactions	O	R	O	R	O	R
Hypoactivity	6-22 H	N	4 H	N	1 H	N
Loss of righting reflex	-	-	5 H	N	2 H	N
Muscular weakness	6-22 H	N	-	-	2 H	N
Ataxia	6-22 H	N	-	-	2 H	N
Prostration	6-22 H	N	-	-	3 H	N
Analgesia	-	-	-	-	3 H	N
Anesthesia	-	-	-	-	4 H	N
Cyanosis	-	-	-	-	4 H	N

O = Onset R = Recovery H = Hours N = No Recovery - = No Reaction

RANGE-FINDING ACUTE DERMAL TOXICITY STUDY - ALBINO RABBITS

Young adult albino rabbits of the New Zealand strain were used as test animals. All rabbits had been maintained under observation in the laboratory for at least 7 days prior to testing. During the pretest period, the animals were examined with respect to their general health and suitability as test animals. The rabbits were housed individually in suspended, wire-bottomed cages and maintained on a standard laboratory ration. Food and water were offered ad libitum.

Twenty-four hours prior to the dermal applications, the backs of the rabbits were shaved free of hair with electric clippers. The shaved area on each animal constituted about 30 percent of the total body surface area. The animals were then returned to their cages to await testing on the following day. The 24-hour waiting period allowed recovery of the stratum corneum from the disturbance which accompanied the close-clipping procedure and permitted healing of any microscopic abrasions possibly produced during the process.

A range of several dose levels was studied using 1 rabbit per level. The test site of each animal was covered by wrapping the trunk with impervious plastic sheeting which was securely taped in place. This plastic wrap insured close contact of the epidermis and test material. To prevent oral ingestion of the test material, each animal was fitted with a lightweight, flexible plastic collar which was worn throughout the observation period.

The test material remained in contact with the skin for 24 hours. At the end of this period, the plastic sheeting and all residual test material were removed. The test sites were examined for local skin reactions and the animals were returned to their cages. Observations for mortality, local skin reactions and behavioral abnormalities were continued for a total of 14 days following the skin applications. Initial, 7- and 14-day body weights were recorded. A necropsy examination was conducted on all animals.

At the end of the observation period, the approximate acute dermal lethal dose of the test material was determined. The test material was then assigned a classification. The classification system is presented below:

Approximate Acute Dermal Lethal Dose (Range of Values)	Classification	Probable Lethal Dose for a 70 kg Man in Commonly Used Measures
Less than 20 mg/kg	Extremely toxic	approximately 30 drops
20 - 200 mg/kg	Highly toxic	between 30 drops and 4 teaspoonfuls
200 - 500 mg/kg	Moderately toxic	between 4 teaspoonfuls and 1 ounce
500 - 3,000 mg/kg	Slightly toxic	between 1 ounce and 1 pint or 1 pound
3,000 - 10,000 mg/kg	Practically nontoxic	between 1 pint and 1 quart
Greater than 10,000 mg/kg	Relatively harmless	more than 1 quart

REPORT TO

M & T CHEMICALS, INC.

Acute Range-Finding Eye Irritation Test - Albino Rabbits

Results

IBT No.: 8530-08644 **Classification:** Not Classifiable
Test Material: Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1
Physical Description: White Powder
Form Administered: Instillation (100 mg, undiluted)
Special Instructions: Unwashed eyes

A. Irritation Scores

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	7 Days
Cornea (D-A)	1	20 (1-4)	-	-	-	-
Iris		5	-	-	-	-
Conjunctiva (R-S-D)		12 (2-1-3)	-	-	-	-
Total		37	-	-	-	-
Cornea (D-A)	2	20 (1-4)	-	-	-	-
Iris		5	-	-	-	-
Conjunctiva (R-S-D)		12 (2-1-3)	-	-	-	-
Total		37	-	-	-	-
Cornea (D-A)	3	20 (1-4)	-	-	-	-
Iris		5	-	-	-	-
Conjunctiva (R-S-D)		12 (2-1-3)	-	-	-	-
Total		37	-	-	-	-

- = Animal died prior to this scoring interval

B. Pharmacotoxic Symptoms

Reaction	Time of Onset Following Dose Administration	Duration of Reaction	Time of Death Following Dose Administration
Miosis	15 Minutes	Until death	3 Hours
Muscular weakness	15 Minutes	Until death	
Lacrimation	15 Minutes	Until death	
Hypoactivity	15 Minutes	Until death	
Labored respiration	1-1/2 Hours	Until death	
Ataxia	1-1/2 Hours	Until death	
Loss of right reflex	1-1/2 Hours	Until death	
Reduced sensory reception (no response to pain)	1-1/2 Hours	Until death	
Tremors	1-1/2 Hours	Until death	
Convulsions	1-1/2 Hours	Until death	
Prostration	2 Hours	Until death	

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by: Ronald G. Baker
Ronald G. Baker, B.S.
Assistant Toxicologist
Acute Toxicity

Report approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

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5/12/76

RANGE-FINDING EYE IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used to evaluate the eye irritating properties of the test material. The test method was patterned after that of Draize, et al*.

The test material was instilled into the conjunctival sac of the right eye of each rabbit. The left eye of each animal served as a control. At each scoring interval, the cornea, iris and palpebral conjunctiva were examined and graded for irritation and injury according to a standard scoring system*. The maximum possible score was 110 points, which indicated maximal irritation and damage to all 3 ocular tissues. Zero score indicated no irritation. The scoring system is presented in Table A. In this scoring system, special emphasis was placed upon irritation or damage to the cornea, while less emphasis was placed upon damage to the iris and conjunctiva.

TABLE A
Eye Irritation Test - Albino Rabbits
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	Opacity (D)	
	Opacity - Degree of density (area which is most dense is taken for reading).	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible, translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	Area of Cornea Involved (A)	
	One quarter (or less) but not 0.	1
	Greater than one quarter but less than one half.	2
	Greater than one half but less than three quarters.	3
	Greater than three quarters to whole area.	4
	Score equals D x A x 5 Total maximum = 80	
Iris	Values	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or a combination of any thereof), iris still reacting to light (sluggish reaction is positive).	1
	No reaction to light, hemorrhage, gross destruction (any or all of these).	2
	Score equals value x 5 Total maximum = 10	
Conjunctiva	Redness (R)	
	Redness (refers to palpebral conjunctiva only).	
	Vessels definitely injected above normal.	1
	More diffuse, deeper crimson red; individual vessels not easily discernible.	2
	Diffuse, beefy red.	3
	Chemosis (S)	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	Discharge (D)	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
	Discharge with moistening of the lids and hairs and considerable area around eye.	3
	Score (R + S + D) x 2 Total maximum = 20	

Note: The maximum total score is the sum of all scores obtained from the cornea, iris and conjunctiva.

* Draize, John H., Woodard, Geoffrey and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," J. Pharm. & Exp. Ther. 82, 377 (1944).

After the completion of the test, the scores were analyzed, and a classification was assigned to the test material. The criteria used for assignment of the classification was the frequency, the extent and the persistence of irritation or damage which occurred to the 3 ocular tissues.

The classification was obtained by selecting the maximum mean irritation score at 1, 24, 48 or 72 hours after instillation. If the rate of dissipation of injury did not meet the requirements defined for the classification appropriate for a particular numerical score, the classification was raised by 1 or more levels. The classification system is presented in Table B.

TABLE B
Eye Irritation Test - Albino Rabbits
Classification of Test Materials
Based on Eye Irritation Properties

Classification	Range	Definition
Nonirritating	0.0 - 0.5	To maintain this rating, all scores at the 24-hour reading must be 0; otherwise, increase rating 1 level.
Practically Nonirritating	Greater than 0.5 - 2.5	To maintain this rating, all scores at the 24-hour reading must be 0; otherwise increase rating 1 level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this rating, all scores at the 72-hour reading must be 0; otherwise, increase rating 1 level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this rating, all scores at the 7-day reading must be 0; otherwise, increase rating 1 level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 20. If 7-day mean score is less than or equal to 20 but less than 60% of animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating 1 level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 40. If 7-day mean score is less than or equal to 40 but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained; otherwise, increase rating 1 level.
Extremely Irritating	Greater than 80.0 - 110.0	

REPORT TO

M & T CHEMICALS, INC.

Acute Range-Finding Primary Skin Irritation Test - Albino Rabbits

Results

IBT No.: 8530-08644 Classification: Not Classifiable
Test Material: Trimethyl-2-carbamylethyltin, Lot No. 3676-33-1
Physical Description: White powder
Form Administered: 500 mg, undiluted
Special Instructions: 24-hour exposure period; occluded sites

Animal Number	Irritation Scores for Abraded Skin Sites at: 24 Hours Er.	24 Hours Ed.	72 Hours Er.	72 Hours Ed.	Irritation Scores for Intact Skin Sites at: 24 Hours Er.	24 Hours Ed.	72 Hours Er.	72 Hours Ed.
1	-	-	-	-	-	-	-	-
2	1	0	-	-*	1	0	-	-*
3	2	0	-	-**	2	0	-	-**

Key: Er. = Erythema
Ed. = Edema
* Died approximately 40 hours after dosing.
** Died approximately 48 hours after dosing.
- = Animal died prior to this scoring interval
Note: Animals 2 and 3 started to exhibit tremors and convulsions several hours after the test material had been washed off. Prior to washing there were no pharmacotoxic symptoms noted.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by: Ronald G. Baker
Ronald G. Baker, B.S.
Assistant Toxicologist
Acute Toxicity

Report approved by: C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

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5/12/76

ACUTE RANGE-FINDING PRIMARY SKIN IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used in the evaluation of the primary skin irritating properties of the test material. The test procedure was modeled after that of Draize et al.*

Prior to the application of the test material, the hair was clipped from the back and flanks of each rabbit. Two test sites located lateral to the midline of the back approximately ten centimeters apart were selected. One of the two sites was abraded by making four epidermal incisions, two perpendicular to the other two, while the other test site remained intact.

The test material was applied to each of the test sites on each rabbit and occluded with gauze patches which were secured with masking tape. The trunk of each animal was then wrapped with impervious plastic sheeting. The wrap held the patches in position and retarded evaporation of the test material during the 24-hour exposure period.

At the end of 24 hours, the plastic wrappings, patches, and all residual test material were removed. The intact and abraded test sites were examined and scored separately for erythema and edema on a graded scale of 0 to 4. After 72 hours, the sites were again examined and scored.

* Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes," J. Pharm. & Exp. Ther. 82, 377 (1944).

In evaluating the average irritation present, the mean scores for erythema and edema of the intact test sites after 24 and 72 hours were added. Similarly, the mean scores for erythema and edema of the abraded test sites after 24 and 72 hours were added. These two values were totaled and divided by four to obtain the mean primary irritation score.

The following grading system was used to arrive at a primary skin irritation classification:

Mean Primary Irritation Score (Range of Values)	Classification
0	Nonirritating
0.1 - 0.5	Minimally Irritating
0.6 - 1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 - 5.0	Moderately Irritating
5.1 - 6.5	Severely Irritating
6.6 - 8.0	Extremely Irritating

The scoring criteria for erythema and edema are shown in the following table:

/

TABLE

Primary Skin Irritation Test - Albino Rabbits

Scoring Criteria for Skin Reactions

Reactions	Description	Score
Erythema	Barely perceptible (Edges of area not defined)	1
	Pale red in color and area definable	2
	Definite red in color and area well defined	3
	Beet or crimson red in color	4
Edema	Barely perceptible (Edges of area not defined)	1
	Area definable but not raised more than 1 mm	2
	Area well defined and raised approximately 1 mm	3
	Area raised more than 1 mm	4
Injury In Depth	Escharosis, Necrosis	8
	Maximum Primary Irritation Score =	8

Industrial **BIO-TEST** *Laboratories, Inc.*
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

AREA CODE 312
TELEPHONE 272-3030

March 26, 1976

Mr. Arthur W. Sheldon
Director of Safety and Environmental Affairs
M & T Chemicals, Inc.
Subsidiary of American Can Company
Rahway, New Jersey 07065

Our Ref.: IBT No. 8530-08644
Your Ref.: Letter of 3/11/76

The following study has been scheduled as indicated below:

Test Material(s):

Trimethyl-2-carbamylethyltin,
Lot No. 3676-33-1

Type of Test(s): Range-Finding Screens:
Acute Oral Toxicity Study - Rats
Acute Dermal Toxicity Study - Rabbits
Eye Irritation Test - Rabbits
Primary Skin Irritation Test - Rabbits

Starting Date: 3/29/76

Termination Date: 4/26/76

Mailing Date: 5/17/76

Project Coordinator: Mr. Carmen W. Mastri

The above dates are approximations, and you will be notified of any delays. If there are any questions, please contact the project coordinator above. Thank you.

Industrial BIO-TEST Laboratories, Inc.
Project Center

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C. H. Farr, PhD, DABT
Manager, Product Safety and Toxicology
Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 0 6 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12661A

Recycled/Recyclable
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Triage of 8(e) Submissions

Date sent to triage: 12/8/95

NON-CAP CAP

Submission number: 12661A

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1,2 **pages** 1,2,4

Notes:

Contractor reviewer : PDR **Date:** 3/13/96

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12661 SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: EIF Atochem North America, Inc.

SUB. DATE: 10/12/92 OTS DATE: 10/26/92 CSRAD DATE: 02/09/95

CHEMICAL NAME: Propamide, 3-(trimethylstannyl)-

CAS#: 60522-55-6

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0670) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
(0243)	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY
YES
CAS SR
NO
(IN TRIAGE)
(COMPLETE)

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RBT
Rat

TOXICOLOGICAL CONCERN:
LOW
MED
(HIGH) Ac. oral, ac. derm eye irr, derm irr

USE:

PRODUCTION:

12661A

H

Acute oral toxicity of trimethyl-2-carbamylethyltin in rats is of high concern based on mortality from single doses to Sprague-Dawley albino rats (1F/dose). Deaths were as follows: at 10 mg/kg, no deaths occurred, and at 30, 100, 300, 1000, and 3000 mg/kg, each animal died. Clinical signs included hypoactivity at all doses; at 30 mg/kg, tremors, hyperirritability and convulsions prior to death; and at 100 mg/kg and greater, labored breathing, muscular weakness, lacrimation, ptosis, salivation, and ruffled fur. Ataxia, prostration, and vasodilation were observed at 3000 mg/kg only. Necropsy showed red, discolored lungs in all animals dying on test, intestinal hemorrhages at 30 and 3000 mg/kg, and enlarged kidneys and emaciation at 30 mg/kg.

H

Acute dermal toxicity in rabbits is of high concern. New Zealand albino rabbits (1M/dose) received applications of 200, 500, or 2000 mg/kg to abraded skin. All animals died within 24 hours. Clinical signs prior to death included hypoactivity, loss of righting reflex, muscular weakness, ataxia, prostration, and at the highest dose only, analgesia, anesthesia, and cyanosis. Necropsy revealed focal hemorrhages of the lungs and dilated renal capillaries at 2000 mg/kg, and advanced postmortem autolysis at the two lower doses.

H

TOXICITY

Eye irritation in rabbits is of high concern based on death following application. Three New Zealand rabbits received a single application of 100 mg of undiluted material to the eye. Death occurred in all three animals within 3 hours. Moderate corneal opacity and edema of the iris and conjunctiva with discharge were noted. Clinical signs prior to death included miosis, muscular weakness, lacrimation, hypoactivity, labored respiration, ataxia, loss of righting reflex, tremors, convulsions, lack of response to pain, and prostration.

H

TOXICITY

Dermal irritation in rabbits is of high concern with death occurring all animals. Three New Zealand albino rabbit received occluded applications of 500 mg undiluted material. One animal died within 24 hours, the other two within 48 hours. Slight to moderate erythema was seen at the application site. Two animals exhibited tremors and convulsions after the material was washed off at 24 hours.